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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,098	06/25/2003	Upul K. Bandarage	102258.154US1	1938

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EXAMINER	
STOCKTON, LAURA LYNNE	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,098	BANDARAGE ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-58 are pending in the application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 14-16, 28-39 and 55, drawn to products of Formula (I) or Formula (II) wherein R_1 is $-S(O)_2-CH_3$, classified in class 548, subclass 356.1+.

II. Claims 1, 2, 14-16, 28-39 and 55, drawn to products of Formula (I) or Formula (II) wherein R_1 is $-S(O)_2-NH_2$, classified in class 548, subclass 356.1+.

III. Claims 1, 2, 14-16, 28-39 and 55 drawn to products of Formula (III) wherein R_1 is $-S(O)_2-CH_3$, classified in class 548, subclass 240+.

IV. Claims 1, 2, 14-16, 28-39 and 55 drawn to products of Formula (III) wherein R_1 is $-S(O)_2-NH_2$, classified in class 548, subclass 240+.

V. Claims 3-13, 17-27, 40-50, drawn to a methods of use by administering products of Formula (I) or Formula (II) wherein R_1 is $-S(O)_2-CH_3$, classified in class 514, subclass 403+.

VI. Claims 3-13, 17-27, 40-50, drawn to a methods of use by administering products of Formula (I) or Formula (II) wherein R_1 is $-S(O)_2-NH_2$, classified in class 514, subclass 403+.

VII. Claims 3-13, 17-27, 40-50, drawn to a methods of use by administering products of Formula (III) wherein R_1 is $-S(O)_2-CH_3$, classified in class 514, subclass 378+.

VIII. Claims 3-13, 17-27, 40-50, drawn to a methods of use by administering products of Formula (III) wherein R_1 is $-S(O)_2-NH_2$, classified in class 514, subclass 378+.

IX. Claims 51-54, drawn to a kit comprising products of Formula (I) or Formula (II) wherein R_1 is $-S(O)_2-CH_3$, classified in class 424.

X. Claims 51-54, drawn to a kit comprising products of Formula (I) or Formula (II) wherein R_1 is $-S(O)_2-NH_2$, classified in class 424.

XI. Claims 51-54, drawn to a kit comprising products of Formula (III) wherein R_1 is $-S(O)_2-CH_3$, classified in class 424.

XII. Claims 51-54, drawn to a kit comprising products of Formula (III) wherein R_1 is $-S(O)_2-NH_2$, classified in class 424.

XIII. Claim 55, drawn to products not embraced by Group I or Group II, classified in class 564.

The inventions are distinct, each from the other because of the following reasons: the products of Groups I-IV and XIII differ materially in structure and element so much so as to be patentably distinct. In

addition, a reference which anticipates one group may not even render obvious the other. The inventions of Groups I-IV and XIII and IX-XII are related as products and a kit. In the instant case, the kit can be practiced with another materially different product. Inventions of Groups I-IV and XIII and Groups V-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product.

Because these inventions are distinct for the reasons given above, and the search required for Group I, for example, is not required for Group II, restriction for examination purposes as indicated is proper.

Therefore, it would impose an undue burden on the Examiner and the Patent Office's resources to examine the instant application if unrestricted.

The above groups themselves are inclusive of patentably distinct subject matter. Accordingly, along with the election of one of the above groups, the following action is also taken.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (e.g., Example number, page number and structural depiction) from whichever group is ultimately elected, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or

clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the election of a single disclosed species (e.g., Example, page number and structural depiction), a scope of the elected invention that has been examined, inclusive of the elected species, will be identified by the Examiner for examination.

Additionally, if a method of use group is elected {e.g., Group V or Group VI or Group VII or Group VIII}, Applicants are also required to elect a single disclose method of using the products. For example:

A) A method of treating asthma; or

B) A method of treating Crohn's disease; or

C) A method of treating colon cancer; or

D) A method of treating breast cancer; or etc.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the**

limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in

order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

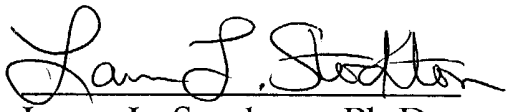
Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



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Patent Examiner
Art Unit 1626, Group 1620
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December 7, 2004